

REMARKS/ARGUMENTS

Claims 2-9, 11-34, 41-48 are in the case. Claims 10 and 35-40 have been cancelled without prejudice, reserving the right to file a continuation application directed to the subject matter of claims 10 and 35-40.

The Examiner has rejected claims 2-16, 19-30, and 34-48 as anticipated by U.S. Pat. No. 6,579,690 to Bonnecaze et al (hereinafter the Bonnecaze reference). Claims 17, 18, 31 and 33 have been rejected over the Bonnecaze reference in view of Publication 2002/0019606, hereinafter the Lebel reference. These rejections are respectfully traversed.

Claim 2 has been amended to incorporate substantially the limitations of original dependent claim 10. Claim 10 has been cancelled without prejudice as set forth above.

Claim 2 as amended is directed to an “infusion system for infusing a fluid into a body of a user, the infusion system comprising ...” *inter alia*, “... a monitoring device processor ...wherein the monitoring device processor is adapted to: determine a first amount of time that has elapsed since the sensor provided the output signal; determine whether the first amount of time exceeds a predetermined amount of time; and, if the first amount of time does not exceed a predetermined amount of time, calculate an amount of the fluid to be infused into the user’s body based upon the output signal, and cause the monitoring device communication circuit to transmit a first set of data indicative of the calculated amount of the fluid to be infused; wherein the monitoring device communication circuit does not transmit a set of data indicative of a calculated amount of fluid to be infused into the user’s body based upon the output signal if the first amount of time exceeds the predetermined amount of time”

It is the Examiner’s position that the Bonnecaze reference discloses a blood analyte monitoring system “substantially” as claimed. The applicants respectfully disagree. For example, the Examiner has failed to cite any portion of the Bonnecaze reference which teaches or suggests a monitoring device processor adapted to “determine a first amount of time that has elapsed since the sensor provided the output signal; determine whether the first amount of time exceeds a predetermined amount of time; and, if the first amount of time does not exceed a predetermined amount of time, calculate an amount of the fluid to be infused into the user’s body based upon the output signal, and cause the monitoring device communication circuit to transmit a first set of data indicative of the calculated amount of the fluid to be infused; wherein the

monitoring device communication circuit does not transmit a set of data indicative of a calculated amount of fluid to be infused into the user's body based upon the output signal if the first amount of time exceeds the predetermined amount of time" as required by claim 2. Such an arrangement can, in one application, for example, help to ensure that the amount of fluid to be infused into the user's body is calculated and transmitted to the medication infusion device for medicating the patient only if the output signal upon which the calculations were based is sufficiently current. It is recognized that for many patients, the concentration of analyte can vary significantly over time.

By comparison, it appears that in the device of the Examiner's citations to the Bonnecaze reference, data is accepted as valid if the "data from the two or more sensors 252 agrees within predetermined parameters." Bonnecaze, col. 55, lines 37 et seq. It is therefore respectfully submitted that the rejection of claim 2 should be withdrawn.

Independent claim 41 may be distinguished in a similar fashion. The rejection of the dependent claims is improper for the reasons given above. Moreover, the dependent claims include additional limitations, which in combination with the base and intervening claims from which they depend, provide still further grounds of patentability over the cited art.

For example, dependent claim 4 further recites "wherein the physiological monitoring device is a blood glucose test strip meter adapted to analyze a test strip exposed to a discrete sample of the analyte of the user to provide a discrete measurement of the analyte in the user." The Examiner has failed to cite any portion of the Bonnecaze reference which teaches or suggests a monitoring device processor adapted to "determine a first amount of time that has elapsed since the sensor [of the blood glucose test strip meter] provided the output signal; determine whether the first amount of time exceeds a predetermined amount of time; and, if the first amount of time does not exceed a predetermined amount of time, calculate an amount of the fluid to be infused into the user's body based upon the output signal [of the blood glucose test strip meter], and cause the monitoring device communication circuit [of the blood glucose test strip meter] to transmit a first set of data indicative of the calculated amount of the fluid to be infused; wherein the monitoring device communication circuit [of the blood glucose test strip meter] does not transmit a set of data indicative of a calculated amount of fluid to be infused into the user's body based upon the output signal [of the blood glucose test strip meter] if the first amount of time exceeds the predetermined amount of time" as required by claim 4.

As a further example, the Examiner has failed to cite any portion of the Bonnecaze reference which teaches or suggests “a blood glucose test strip meter adapted to analyze a test strip exposed to a discrete sample of the analyte of the user to provide a discrete measurement of the analyte in the user.” Instead, it is believed that the sensors of the Examiner’s citations to the Bonnecaze reference provide continuous blood glucose data rather than discrete blood glucose measurements. In those applications in which a blood glucose test strip meter provides discrete measurements of the analyte in the user, it is recognized by the present applicants that it can be particularly advantageous to ensure that the amount of fluid to be infused into the user’s body is calculated and transmitted to the medication infusion device for medicating the patient only if the output signal upon which the calculations were based is sufficiently current. Dependent claim 42 may be distinguished in a similar fashion.

Still further, with respect to the 103 rejections of dependent claims 17, 18, 31 and 33, based upon a combination of the Bonnecaze and Lebel references, it is noted that the Lebel reference, like the Bonnecaze reference, has been applied by the Examiner as a 102(e) reference. It is respectfully submitted that the subject matter of the Lebel reference applied as a 102(e) reference, will not preclude patentability under section 103 of the patent statute because, in addition to the reasons set forth above, it is the understanding of the undersigned, that the subject matter of the Lebel reference and the presently claimed inventions of dependent claims 17, 18, 31 and 33 were, at the time the claimed inventions were made, owned by the same person or subject to an obligation of assignment to the same person.

More specifically, it is the understanding of the undersigned that the subject matter of the Lebel reference was at the time the claimed inventions were made, assigned to Medical Research Group Inc., a wholly owned subsidiary of Medtronic, Inc. An assignment of the Lebel reference to Medical Research Group Inc. is recorded at reel/frame 012244/0315. Furthermore, it is the understanding of the undersigned that the presently claimed inventions of dependent claims 17, 18, 31 and 33 were at the time the claimed inventions were made, assigned to or subject to an obligation of assignment to Medtronic Minimed, Inc, also a wholly owned subsidiary of Medtronic, Inc. An assignment of the present application is recorded at reel/frame 015277/0435. Accordingly, it is the understanding of the undersigned that the subject matter of the Lebel reference and the presently claimed inventions of dependent claims 17, 18, 31 and 33 were, at the time the claimed inventions were made, owned by the same person or subject to an

obligation of assignment to the same person, that is, Medtronic, Inc. It is therefore respectfully submitted that the rejection of dependent claims 17, 18, 31 and 33 should be withdrawn.

The Examiner has made various comments concerning the anticipation or obviousness of certain features of the present inventions. Applicants respectfully disagree. Applicants have addressed those comments directly hereinabove or the Examiner's comments are deemed moot in view of the above response.

Conclusion

For all the above reasons, Applicants submit that the pending claims 2-9, 11-34, 41-48 are patentable over the art of record. Applicants have not added any claims. Nonetheless, should any additional fees be required, please charge Deposit Account No. 50-0585.

The attorney of record invites the Examiner to contact him at (310) 553-7970 if the Examiner believes such contact would advance the prosecution of the case.

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